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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/029,551
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		Examiner Name	Christine J. Saoud
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U.S. PATENT DOCUMENTS

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A42	5,023,077	06/11/91	Gevas et al.	424	88	
	A43	5,189,049	02/23/93	Frehel et al.	514	371	
	A44	5,290,920	03/01/94	Sindrey et al.	530	412	
	A45	5,624,895	04/29/97	Sobel	514	8	
	A46	6,242,666 B1	06/05/01	Sarvetnick et al.	800	18	
	A47	6,326,201 B1	12/04/01	Fung et al.	435	377	
	A48	6,413,952 B1	07/02/02	Luengo et al.	514	184	

U.S. PUBLISHED APPLICATION DOCUMENTS

Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A49	2003/0049236 A1	03/13/03	Kassem et al.	424	93.21	
	A50	2003/0083259 A1	05/01/03	Efendic et al.	514	12	
	A51	2003/0119734 A1	06/26/03	Flink et al.	514	12	
	A52	2003/0224983 A1	12/04/03	Nielsen	514	12	

FOREIGN PATENT DOCUMENTS

Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	B30	EP 0 044 168 B1	Novo Nordisk	01/01/82	
	B31	EP 0 161 816	Imperial Chemical Industries	11/21/85	
	B32	WO 95/31214	London Health Sciences	11/23/95	
	B33	WO 98/14203	Amrad Operations Pty. Ltd	04/09/98	
	B34	WO 02/12452 A2	Curis Inc.	02/14/02	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C108	Adams et al., "Insulin-like growth factor-I promotes successful fetal pancreas transplantation in the intramuscular site", <i>Surgery</i> , 116:751-757 (1994)
	C109	Ahmed et al., "High and Low Affinity Receptors Mediate Growth Effects of Gastrin and Gastrin-Gly on DLD-1 Human Colonic Carcinoma Cells", <i>FEBS Letters</i> , 556:199-203 (2004)
	C110	Alpert et al., "Hybrid Insulin Genes Reveal a Developmental Lineage for Pancreatic Endocrine Cells and Imply a Relationship with Neurons", <i>Cell</i> , 53:295-308 (1988)
	C111	Baggio et al., "Sustained Expression of Exendin-4 Does Not Perturb Glucose Homeostasis, b-Cell Mass, or Food Intake in Metallothionein-Preproexendin Transgenic Mice", <i>J Biol Chem</i> , 275(44):34472-34477 (2000)
	C112	Baggio et al., "Therapeutic approaches to preserve islet mass in type 2 diabetes", <i>Annual Review of Medicine</i> , 57:265-281 (2006)
	C113	Bentley et al., "Human Gastrin: Isolation, Structure and Synthesis", <i>Nature</i> , 209:583-585 (1966)
	C114	Berendsen, H.J.C., "A glimpse of the Holy Grail?", <i>Science</i> , 282:642-643 (1998)
	C115	Blömer et al., "Applications of Gene Therapy to the CNS", <i>Human Molecular Genetics</i> , 5:1397-404 (1996)
	C116	Bonato et al., "Guinea Pig 33-Amino Acid Gastrin", <i>Life Science</i> , 39:959-964 (1986)
	C117	Bonner-Weir et al., "In vitro cultivation of human islets from expanded ductal tissue", <i>PNAS</i> , 97(14): 7999-8004 (2000)
	C118	Bonner-Weir, S. J., "Islet Growth and Development in the Adult", <i>Mol. Endocrinol.</i> , 24:297-302 (2000)
	C119	Boshart et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus", <i>Cell</i> , 41:521-530 (1985)
	C120	Bouwens et al., "Identification of Rat Pancreatic Duct Cells by Their Expression of Cytokeratins 7, 19 and 20 in Vivo and After Isolation and Culture", <i>J Histochemistry and Cytochemistry</i> , 43(3):245-253 (1995)
	C121	Brand et al., "Prolonged Efficacy of Islet Neogenesis Therapy with Gastrin and TGF α in Mature Rats with Preexisting Diabetes", <i>Diabetes</i> , 50(Suppl 2):A338 (Abstract) (2001)
	C122	Brejie et al., "The Physiological Role of Prolactin, Growth Hormone and Placental Lactogen in the Regulation of Islet b Cell Proliferation", Chapter 1, pp 1-30, in <i>Pancreatic Growth and Regeneration</i> , Karger Landes Systems (1997)
	C123	Carlsson et al., "Gastrin and gastric enterochromaffin-like cell carcinoids in the rat", <i>Digestion</i> , 47(Suppl 1):17-23, "Discussion", pp 49-52 (1990)
	C124	Carlsson et al., "Protein Thiolation and Reversible Protein-Protein Conjugation N-Succinimidyl 3-(2-Pyridyldithio):Propionate, A New Heterobifunctional Reagent", <i>Biochem J</i> , 173:723-737 (1978)
	C125	Chedid et al., "Regulation of Keratinocyte Growth Factor Gene Expression by Interleukin 1", <i>J Biol Chem</i> , 269:10753-10757 (1994)
	C126	Chen et al., "Time course of hypertrophic and ultrastructural responses of rat stomach enterochromaffin-like cells to sustained hypergastrinemia", <i>Cell Tissue Res</i> , 284(1):55-63 (1996)
	C127	Cordell et al., "Isolation and Characterization of a Cloned Rat Insulin Gene", <i>Cell</i> , 18:533-543 (1979)
	C128	Creutzfeldt et al., "Is hypergastrinaemia dangerous to man?", <i>Scand J Gastroenterol Suppl.</i> , 26(Suppl. 180):179-191 (1991)

	C129	Di Lorenzo et al., "Involvement of growth factor receptors of the epidermal growth factor receptor family in prostate cancer development and progression to androgen independence", <i>Clin. Prostate Cancer</i> , 2(1):50-57 (2003)
	C130	Dinsmoor, R.S., "The endless possibilities of β cell regeneration", <i>JDRF Countdown</i> , 8-18 (2005)
	C131	Drumm et al., "Urogastrone/epidermal growth factor in treatment of congenital microvillous atrophy", <i>The Lancet</i> , 1(8577):111-112 (1988)
	C132	Efrat, S., "Prospects for gene therapy of insulin-dependent diabetes mellitus", <i>Diabetologia</i> , 41:1401-1409 (1998)
	C133	Elder et al., "Effect of urogastrone in the Zollinger-Ellison syndrome", <i>The Lancet</i> , 2(7932):424-427 (1975)
	C134	Elder et al., "Effect of urogastrone on gastric secretion and plasma gastrin levels in normal subjects", <i>Gut</i> , 16(11):887-893 (1975)
	C135	Fellenius et al., "Substituted Benzimidazoles Inhibit Gastric Acid Secretion by Blocking (H^+ + K^+)ATPase", <i>Nature</i> , 290:159-161 (1981)
	C136	Fryklund et al., "Function and Structure of Parietal Cells After H^+ , K^+ -ATPase Blockade", <i>Am. J. Physiol.</i> , 254(3 PT 1):G399-G407 (1988)
	C137	Gajdosik et al., "Streptozotocin-Induced Experimental Diabetes in Male Wistar Rats", <i>Gen Physiol Biophys</i> , 18:54-62 (1999)
	C138	GenBank Accession, No. AAH69762, Strausberg et al., "Generation and initial analysis of more than 15,000 full-length human and mouse cDNA sequences", <i>Gene Sequence</i> (2006)
	C139	GenBank Accession, No. NP_000796, Stone et al., "Evidence for a C-terminal structural motif in gastrin and its bioactive fragment in membrane mimetic media", <i>Gene Sequence</i> (2007)
	C140	Gmyr et al., "Human Pancreatic Ductal Cells: Large-Scale Isolation and Expansion", <i>Cell Transplantation</i> , 10:109-121 (2001)
	C141	Green et al., "Effect of Dynorphin on Insulin and Somatostatin Secretion, Calcium Uptake, and c-AMP Levels in Isolated Rat Islets of Langerhans", <i>Diabetes</i> , 32:685-690 (1983)
	C142	Gregory et al., "The Contribution of the C-terminal Undecapeptide Sequence of Urogastrone-Epidermal Growth Factor to its Biological Action", <i>Regulatory Peptides</i> , 22:217-226 (1988)
	C143	Gregory et al., "The Isolation of the Urogastrones-Inhibitors of Gastric Acid Secretion--from Human Urine", <i>Hoppe-Seyler's Z. Physiol. Chem.</i> , Bd., 356:1765-1774, (1975)
	C144	Hollenberg et al., "Epidermal Growth Factor-Urogastrone: Biological Activity and Receptor Binding of Derivatives", <i>Molecular Pharmacology</i> , 17:314-320 (1980)
	C145	Jensen, R., "Gastrinoma as a model for prolonged hypergastrinemia in the human", Chapter 29, pp 373-393, Raven Press Ltd., New York (1993)
	C146	Jhappan et al., "TGF α Overexpression in Transgenic Mice Induces Liver Neoplasia and Abnormal Development of the Mammary Gland and Pancreas", <i>Cell</i> , 61:1137-1146 (1990)
	C147	Kajimoto et al., "Pancreas Morphogenetic Gene and the Abnormality thereof", <i>G.I. Research</i> , 9(3):1-14 (2001)
	C148	Kaufman et al., "Construction of a Modular Dihydrofolate Reductase cDNA Gene: Analysis of Signals Utilized for Efficient Expression", <i>Molecular and Cellular Biology</i> , 2(11):1304-1319 (1982)
	C149	Kolb, H., "Mouse Models of Insulin Dependent Diabetes: Low-Dose Streptozocin-Induced Diabetes and Nonobese Diabetic (NOD) Mice", <i>Diabetes Metab Rev</i> , 3(3):751-778 (1987)
	C150	Kopin et al., "The role of the cholecystokinin-B/gastrin receptor transmembrane domains in determining affinity for subtype-selective ligands", <i>J Biol Chem</i> , 270(10):5019-5023 (1995)
	C151	Korc et al., "Regulation of Protein Synthesis in Normal and Diabetic Rat Pancreas by Cholecystokinin", <i>Am J Physiol</i> , 241:G116-G121 (1981)

	C152	Krakowski et al., "Transgenic Expression of Epidermal Growth Factor and Keratinocyte Growth Factor in Beta-Cells Results in Substantial Morphological Changes", <i>J Endocrinol</i> , 162:167-175 (1999)
	C153	Kuntz et al., "Cholecystokinin Octapeptide: A Potential Growth Factor for Pancreatic Beta Cells in Diabetic Rats", <i>Journal of Pancreas</i> , 5(5):464-475 (2004)
	C154	Lakey et al., "Intraductal Collagenase Delivery Into the Human Pancreas Using Syringe Loading or Controlled Perfusion", <i>Cell Transplant</i> , 8:285-292 (1999)
	C155	Lin et al., "A71378: a CCK agonist with high potency and selectivity for CCK-A Receptors", <i>Am J. Physiol.</i> , 258(4-pt.1):G648-G651 (1990)
	C156	Lingohr et al., "Activation of IRS-2-Mediated Signal Transduction by IGF-1, but Not TGF- Alpha or EGF, Augments Pancreatic Beta-Cell Proliferation", <i>Diabetes</i> , 51:966-976 (2002)
	C157	Lumelsky et al., "Differentiation of Embryonic Stem Cells to Insulin-Secreting Structures Similar to Pancreatic Islets", <i>Science</i> , 292:1389-1394 (2001)
	C158	Martindale: The Extra Pharmacopoeia, 13 th Edition, pp 896-898, The Pharmaceutical Press, London, (1993)
	C159	Maton et al., "Long-Term Efficacy and Safety of Omeprazole in Patients With Zollinger- Ellison Syndrome: a Prospective Study", <i>Gastroenterology</i> , 97:827-836 (1989)
	C160	Metz et al., "Proton pump activation in stimulated parietal cells is regulated by gastric acid secretory capacity: a human study", <i>J. Clin. Pharmacol.</i> , 42:512-519 (2002)
	C161	Miettinen et al., "Impaired migration and delayed differentiation of pancreatic islet cells in mice lacking EGF-receptors", <i>Development</i> , 127:2617-2627 (2000)
	C162	Mode et al., "The Human Growth Hormone (hGH) Antagonist ^{G120R} hGH Does Not Antagonize GH in the Rat, But Has Paradoxical Agonist Activity, Probably Via the Prolactin Receptor", <i>Endocrinol.</i> , 137(2):447-454 (1996)
	C163	Morley et al., "Polypeptides. Part IX. Variations of the Methionyl Position in the C-terminal Tetrapeptide Amide Sequence of the Gastrins", <i>J. Chem. Soc.</i> , pp 726-733 (1968)
	C164	Nauck et al., "Additive Insulinotropic Effects of Exogenous Synthetic Human Gastric Inhibitory Polypeptide and Glucagon-Like Peptide-1-(7-36) Amide Infused at Near-Physiological Insulinotropic Hormone and glucose Concentrations", <i>J. of Clin. Endo. and Meta.</i> , 76(4):912-917 (1993)
	C165	Nauck et al., "Preserved Incretin Activity of Glucagon-like Peptide 1 [7-36 Amide] but Not of Synthetic Human Gastric Inhibitory Polypeptide in Patients with Type-2 Diabetes Mellitus", <i>J. Clin. Invest.</i> , 91:301-307 (1993)
	C166	Nielsen et al., "Beta Cell Proliferation and Growth Factors", <i>J Mol Med</i> , 77:62-66 (1999)
	C167	Normanno et al., "EGF-related peptides in the pathophysiology of the mammary gland", <i>J. Mammary Gland Biol. Neoplasia</i> , 2(2):143-151 (1997)
	C168	Ohishi et al., "Structure of 5-Methoxy-2-{[4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl}-1 <i>H</i> -benzimidazole (Omeprazole)", <i>Acta Cryst.</i> , C45:1921-1923 (1989)
	C169	Ohlsson et al., "The Effect of Intermittent Injections of CCK-8S and the CCK-A Receptor Antagonist Devazepide on Cell Proliferation in Exocrine Rat Pancreas", <i>Int J Pancreatol</i> , 24(3):211-218 (1998)
	C170	Ohlsson et al., "The Method of Administration of Cholecystokinin Determines the Effects Evoked in the Pancreas", <i>Pancreas</i> , 23(1):94-101 (2001)
	C171	Orbuch et al., "Prolonged hypergastrinemia does not increase the frequency of colonic neoplasia in patients with Zollinger-Ellison syndrome", <i>Dig. Dis. Sci.</i> , 41(3):604-613 (1996)
	C172	Orskov et al., "Tissue and Plasma Concentrations of Amidated and Glycine-Extended Glucagon-Like Peptide-1 in Humans", <i>Diabetes</i> , 43:535-539 (1994)
	C173	Patel et al., "Treatment of non-insulin-dependent diabetes mellitus", <i>Expert Opinion Investig Drugs</i> , 12(4):623-633 (2003)

	C174	Pederson et al., "Effect of Cholecystokinin, Secretin, and Gastric Inhibitory Polypeptide on Insulin Release From the Isolated Perfused Rat Pancreas", <i>Can J Physiol Pharmacol</i> , 57:1233-1237 (1979)
	C175	Pictet et al., "Development of the embryonic endocrine pancreas", in <i>Handbook of Physiology: Endocrinology</i> , Chapter 2, pp 25-66 (1972)
	C176	Pratha et al., "Inhibition of pentagastrin-stimulated gastric acid secretion by pantoprazole and omeprazole in healthy adults", <i>Digestive Diseases and Sciences</i> , 51(1):123-131 (2006)
	C177	Proietto et al., "Glucose Utilization in Type 1 (Insulin-Dependent) Diabetes: Evidence for a Defect not Reversible by Acute Elevations of Insulin", <i>Diabetologia</i> , 25(4):331-335 (1983)
	C178	Reilly, J., "Safety profile of the proton-pump inhibitors", <i>Am. J. Health Syst. Pharm.</i> , 56(Suppl. 4): S11-S17 (1999)
	C179	Ricordi et al., "Automated Method for Isolation of Human Pancreatic Islets", <i>Diabetes</i> , 37:413-420 (1988)
	C180	Robbins et al., "Viral Vectors for Gene Therapy", <i>Trends in Biotechnology</i> , 16:35-40 (1998)
	C181	Schally et al., "New approaches to therapy of cancers of the stomach, colon and pancreas based on peptide analogs", <i>Cell. Mol. Life Sci.</i> , 61(9):1042-1068 (2004)
	C182	Scheving et al., "Circadian phase-dependent stimulatory effects of epidermal growth factor on deoxyribonucleic acid synthesis in the tongue, esophagus, and stomach of the adult male mouse", <i>Endocrinology</i> , 105:1475-1480 (1979)
	C183	Schmied et al., "Differentiation of Islet Cells in Long-Term Culture", <i>Pancreas</i> , 20(4):337-347 (2000)
	C184	Seva et al., "Growth-Promoting Effects of Glycine-Extended Progastrin", <i>Science</i> , 265:410-412 (1994)
	C185	Sharp et al., "Transforming growth factor alpha disrupts the normal program of cellular differentiation in the gastric mucosa of transgenic mice", <i>Development</i> , 121:149-161 (1995)
	C186	Singh et al., "Novel Gastrin Receptors Mediate Mitogenic Effects of Gastrin and Processing Intermediates of Gastrin on Swiss 3T3 Fibroblasts", <i>J. Biol Chem</i> , 270(15):8429-8438 (1995)
	C187	Sjoholm et al., "TGF-Beta Stimulates Insulin Secretion and Blocks Mitogenic Response of Pancreatic Beta-Cells to Glucose", <i>Am J Physiol</i> , 260:C1046-C1051 (1991)
	C188	Sjoholm A., "Diabetes mellitus and Impaired Pancreatic Beta-cell proliferation", <i>Journal of Internal Medicine</i> , 239(3):211-220 (1996)
	C189	Smith et al., "Review article: gastrin and colorectal cancer", <i>Ailment Pharmacol. Ther.</i> , 14:1231-1247 (2000)
	C190	Suarez-Pinzon et al., "Combination therapy with epidermal growth factor and gastrin induces neogenesis of human islet beta cells from pancreatic duct cells and an increase in functional beta-cell mass", <i>J Clin Endocrinol & Metabolism</i> , 90(6):3401-3409 (2005)
	C191	Suarez-Pinzon et al., "Testicular Sertoli Cells Protect Islet B-cells from Autoimmune Destruction in NOD Mice by a Transforming Growth Factor-B-1-Dependent Mechanism", <i>Diabetes</i> , 49:1810-1818 (2000)
	C192	Subramani et al., "Expression of the Mouse Dihydrofolate Reductase Complementary Deoxyribonucleic Acid in Simian Virus 40 Vectors", <i>Molecular and Cellular Biology</i> , 1(9):854-864 (1981)
	C193	Sullivan et al., "Epidermal growth factor in necrotizing enteritis [letter]", <i>The Lancet</i> , 338(8758):53-54 (1991)
	C194	Thomas et al., "Role of gastrointestinal hormones in the proliferation of normal and neoplastic tissues", <i>Endocr. Rev.</i> , 24(5):571-599 (2003)
	C195	Tomioka et al., "Cellular and subcellular localization of transforming growth factor- α and epidermal growth factor receptor in normal and diseased human and hamster pancreas", <i>Teratogenesis, Carcinogenesis and Mutagenesis</i> , 15:231-250 (1995)

	C196	"Transition Therapeutics Confirms Effectiveness of Islet Neogenesis Therapy in Reducing Diabetic Symptoms", Transition Therapeutics Press Release, April 17, 2002
	C197	"Transition Therapeutics Inc. Receives Approval to Initiate Phase I Clinical Trial for Islet Neogenesis Therapy", Transition Therapeutics Press Release, September 20, 2002
	C198	"Transition Therapeutics' I.N.T.™ Treatment Stimulates Regeneration of Human Insulin-Producing Cells", Transition Therapeutics Press Release, September 26, 2002
	C199	"Transition Therapeutics' I.N.T.™ Treatment Increases Survival", Transition Therapeutics Press Release, September 27, 2002
	C200	Unger et al., "The Effects of Secretin, Pancreozymin, and Gastrin on Insulin and Glucagon Secretion in Anesthetized Dogs", <i>Journal of Clinical Investigation</i> , 46(4):630-645 (1967)
	C201	Wallmark et al., "The Relationship Between Gastric Acid Secretion and Gastric H ⁺ , K ⁺ -ATPase Activity", <i>J. Biol. Chem.</i> , 260(25):13681-13684 (1985)
	C202	Wank et al., "Cholecystokinin Receptor Family. Molecular Cloning, Structure, and Functional Expression in Rat, Guinea Pig, and Human", <i>Ann N Y Acad Sci</i> , 713:49-66 (1994)
	C203	Wank et al., "Purification, molecular cloning, and functional expression of the cholecystokinin receptor from rat pancreas", <i>Proc. Natl. Acad. Sci.</i> , 89(7):3125-3129 (1992)
	C204	Wank S.A., "Cholecystokinin Receptors", <i>Am J Physiol</i> , 269:G628-G646 (1995)
	C205	Whitaker et al., "Polymeric Delivery of Protein-Based Drugs", <i>Bus Brief: Pharmatech</i> , pp 1-5 (2002)
	C206	Xu et al., "Gastrin/CCK-B receptor is involved in the promoting effects of acid-suppressing drugs on regenerating endocrine pancreas", <i>Pancreatic Disorders</i> , A495 (Abstract) (1997)
	C207	Zabner et al., "Adenovirus-Mediated Gene Transfer Transiently Corrects the Chloride Transport Defect in Nasal Epithelia of Patients with Cystic Fibrosis", <i>Cell</i> , 75:207-216 (1993)

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	
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